REMARKS

Claims 1-6, 12-16, 22-26, 32-36 42-46, 52-56, 62-66, 72-76, 78-82, 84-88, 90-94, 96-100, 102-106 and 108-112 are currently pending. With this paper claims 1, 12, 22, 32, 42, 52 and 62 have been amended. No new matter enters by way of these amendments.

Applicants note that the amendments filed on September 1, 2005 have not been entered. In accordance with MPEP 706.07(h) V, Applicants request that the after final amendments filed September 1, 2005 not be entered, but rather the present amendments, which incorporate the previously submitted, but unentered after final amendments, be entered.

Applicants acknowledge Examiner's finding in the Advisory Action that the proposed after final amendments filed on September 1, 2005, would overcome the rejection of claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56 62-66, 72, 76, 78, 82, 84, 88, 90, 94, 96, 100, 102, 106, 108, and 112 under 25 U.S.C. 112, first paragraph (written description) set forth in the Office action of June 7, 2005. Applicants also acknowledge finding that the proposed after final amendments filed on September 1, 2005, would overcome the rejection of claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 76, 78, 82, 84, 88, 90, 94, 96, 100, 102, 106, 108, and 112 under 35 U.S.C. 112, first paragraph (enablement) set forth in the Office action of June 7, 2005.

Applicants also acknowledge the Examiner's agreement that when the instant claims are otherwise allowable, the provisional obviousness-type double patenting rejection set forth in the Office action June 7, 2005 and that Applicants' statement in the response filed September 1, 2005 satisfies the requirement set forth in section 6 of the Office action of June 7, 2005.

Rejections Under 35 U.S.C. Second Paragraph

In the Advisory Action, claims 1, 12, 22, 32, 42, 52 and 62 were rejected under 35 U.S.C. 112, second paragraph, for lack of antecedent basis for the phase "said at least one symptom of PCOS." With this paper, claims 1, 12, 22, 32, 42, 52, and 62 have been amended to delete the word "said." Applicants submit that with this amendment, the claims fully comply with section 112, second paragraph and request reconsideration and withdrawal of the rejection.

Entitlement to Priority

In the Advisory Action, the finding that claims 4, 14, 24, 34, 44, 54, 64, 74, 76, 80, 82, 86, 88, 92, 94, 98, 100, 104, 106, 110, and 112 are not entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 10/317,126 (the '126 application) because the parent application does not meet the requirements of 35 U.S.C. 112, first paragraph, was maintained. Applicants respectfully disagree with this finding.

Applicants restate and incorporate the their arguments submitted in the response filed September 1, 2005. In the Advisory Action, it is maintained that the Office has not made a blanket statement of a lack of written description, but has provided an analysis with citations to applicants' specification in section 7 of the final Office action of June 7, 2005. Applicants respectfully disagree. In section 7, the final Office action alleges that the '126 parent application does not disclose the use of exendins in general, the use of exendin-4 acid, and the use of all exendins having SEQ ID Nos 20-27. Applicants disagree that the '126 application is limited to three specific exendins. For example, the '126 parent application as well as the grandparent 60/350,395 provisional application (the '395 application) state that the invention includes molecules that bind to or activate a GLP-1 receptor (paragraph [0030]), and GLP-1 agonists including exendin-4 (paragraph [0012]). At the time the parent application was filed, it was known in the art that exendins are GLP-1 agonists that bind to and activate the GLP-1 receptor. See, Goke et al., *J. Biol. Chem.*, 268:19650-19655, 1993; Fehmann et al., *Peptides*, 15:453-456, 1994; Schepp et al., *Eur. J. Pharmacol.*, 269:183-191, 1994. Further, paragraph [0034] of both parental applications provides that molecules included in the invention include six exendin peptides listed in Table 1. Applicants wish to point out that helospectin and helodermin are alternative names for exendin 1 and exendin 2, respectively. Thus, one of skill in the art, reading the specification would conclude that the invention includes more than just the specific sequences provided in the application.

The final Office action concludes that the "[d]isclosure of a few species does not provide support for the more generic claim terminology or for the other patentably distinct species currently claimed. Applicants submit that this is a blanket statement and further it is an incorrect

statement of the law. The Office is again direct to the recent case of *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005) cited by Applicants in the response filed September 1, 2005. In that case, the Board of Patent Appeals upheld a Patent Office finding that the applications in question did not meet the written description requirement because of a failure to provide the complete nucleotide sequence of chimeric genes when the component DNA of the genes was known. In vacating the Board's decision, the Federal Circuit stated that "[t]he 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge [in the art]. The Board's rule that the nucleotide sequence of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. When the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh." *Capon* at 1358. In discussing what is needed to meet the written description requirement, the Court noted that amount of description "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science." *Capon* at 1357. The Court further noted that the written description requirement does not "require a re-description of what was already known." *Id.*

The holding in *Capon* is consistent with court decisions going back to *Webster Loom v. Higgins*, 105 US 580 (1881) previously cited by the Applicants. In that case, the Supreme Court held that in describing an invention in such full, clear and exact terms as to enable person skilled in the art to construct and use it, "that which is common and well known is if it were written out in the patent and delineated in the drawings." *Id.* at 586. *Webster Loom* was cited in *In re Folkers*, 344 F.2d 970, 976 (C.C.P.A. 1965) which held that in the context of the written description requirement "[i]t is well settled that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by person skilled in the art." Specifically in the context of what is necessary under 35 U.S.C. 112, first paragraph, to support a benefit of priority, the Federal Circuit has held that "[a] patent need not include in the specification that which is already known to and available to the public." *Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659, 664 (Fed. Cir.

1986). It is undisputed that at the time of filing of the parent application, a large number of exendin analogs were known in the art as exemplified by the International Patent Application Publications previously cited by the Applicants. In the Advisory Action, it is noted that these publications were not incorporated by reference into the parent application. Applicants wish to point out, however, that none of the above cited cases require incorporation by reference.

In addressing the cited International Patent Application publications, the Advisory Action states that the publications embrace a large number of exendin analogs, the exendin analogs are not described as GLP-1 agonists, and that the use of the exendin agonists for treatment PCOS is not described. Regarding the large number of exendin analogs described in the cited publications, Applicants note that the Advisory Action confirms that large numbers of exendin analogs were known in the art. Addressing the allegation that the cited International publications do not identify the analogs as GLP-1 receptor agonists, Applicants must respectfully disagree. Applicants note that all three publications state that exendin-4 works by binding to the GLP-1 receptor. Additionally each application provides evidence of exemplary exendin analogs that bind to cells expressing the GLP-1 receptor resulting in cyclase activation. Thus, the analogs described in the cited publication clearly bind to or activate a GLP-1 receptor as contemplated by the '395 and '126 parental applications. Regarding the use of the compounds, the International Publications are not cited for their description of the use exendin analogs to treat PCOS, that is provided by the '395 and '126 parental application themselves, but rather to show that numerous peptides that bind to or activate the GLP-1 were known in the art at the time the parent applications were filed.

With respect to the citation to *In re Howarth*, 654 F.2d 103 (C.C.P.A 1981) cited by the Applicants in the response of September 1, 2005, the Advisory Action states that *Howarth*, concerns that enablement provision of 35 U.S.C. 112, first paragraph, and its holding and analysis do not apply to the written description requirement. Without agreeing to the applicability of *Howarth*, Applicants note that in the Final Office action of June 7, 2005, the benefit of priority to the '126 application was denied because it was alleged the '126 application does not disclose the administration of exendin peptides in general, the use of exendin-4 acid, and does not disclose the exendins of SEQ ID NOS. 20-27. The reference to the administration

and use of exendins implicates the enablement provision of section 112, first paragraph. If by the language of the Advisory Action, the Examiner means that the parent '126 application fully enables the present application, Applicants acknowledge this finding, thank the Examiner, and direct the Patent Office to the cases cited above and previously that address the requirements of section 112, first paragraph in general, or the written description requirement in particular. If the Examiner is of the opinion that enablement issues remain, the citation to *Howarth* in Applicants' previous response is relevant and is incorporated herein. Moreover, *Howarth* is relevant to the sources of information one skilled in the art would be expected to consult. Applicants are unaware of any case holding that the characteristics of one skilled in the art differ depending upon which provision of 35 U.S.C. 112, first paragraph, is in question. Thus, Applicants submit that if the skilled artisan is expected to consult patent applications for enablement as stated in *Howarth*, that same skilled artisan would be expected to consult patent applications for written description.

In summary, Applicants respectfully submit that all of the present claims are entitled to the benefit of priority of the both the '395 and '126 applications. As discussed above, both applications set forth the use of peptides that bind to or activate the GLP-1 receptor for the treatment of PCOS. Both applications provide that exendins meet these criteria and provide specific examples of several exendins that can be used. In addition, at the time of filing the '395 and '126 applications, numerous additional exendin peptides that bind to and activate the GLP-1 receptor were known in the art. Thus, Applicants respectfully request reconsideration and withdrawal of the finding that claims 4, 14, 24, 34, 44, 54, 64, 74, 76, 80, 82, 86, 88, 92, 94, 98, 100, 104, 106, 110, and 112 are not entitled under 35 U.S.C. 120 to the benefit of priority of the filing date of the parent 10/317,126 application.

Rejections Under 35 U.S.C. 102

In the Advisory Action, the rejection of claims 4, 14, 24, 34, 44, 54, 64, 74, 76, 80, 82, 86, 88, 92, 94, 98, 100, 104, 106, 110, and 112 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2004/0029784 which corresponds to Serial Number

10/317,126 was maintained. Applicants respectfully traverse this rejection and incorporate the arguments made in the response filed September 1, 2005 herein.

As discussed above, all of the presently pending claims are entitled to the benefit of the filing date of the parent applications, and as such, the '784 Publication does not constitute prior art under 35 USC § 102(e). Further, even if the claims were not entitled to the benefit of the parent applications, which Applicants do not concede, then likewise, the parent application does not anticipate such subject matter because anticipation requires disclosure of each and every element. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

In the Advisory Action, the rejection of claims 4, 14, 76, 77, 82 and 83 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2004/0180824 was maintained. Applicants respectfully traverse this rejection and incorporate the arguments made in the response filed September 1, 2005 herein. As discussed above, the present claims are entitled to the benefit of the priority to the 60/350,395 application filed January 22, 2002. As such, U.S. Patent Application Publication 2004/0180824 is not prior art. For at least these reasons, reconsideration and withdrawal of this rejection is respectfully requested.

Claim Objections

In the final Office action of June 7, 2005 and the Advisory Action of September 14, 2005, claims 74, 80, 86, 92, 98, 104 and 110 are listed as being objected to. Applicants have examined both the final Office action and the Advisory Action and can find no specific ground for these objections listed. Applicants therefore respectfully request that the Patent Office provide such specific grounds or withdraw the objections.